REMARKS

Claims 1-5, 7-14, 16-23, 25-28, and 30 are pending. Claims 1, 10, 19, 20, 25, and 30 have been amended. Claims 1-5, 7-14, 16-23, 25-28, and 30 remain in the case. No new matter has been introduced.

An Information Disclosure Statement citing further art references was filed on September 22, 2003, prior to the mailing date of a final action under 37 C.F.R. 1.113. The Information Disclosure Statement must be considered on the record. 37 C.F.R. 1.97(c). Acknowledgement of the Information Disclosure Statement and entry of the cited art references are requested.

Preliminarily, Claims 1, 10, 19, 20, 25, and 30 have been amended to address the 35 U.S.C. 112, first and second paragraph rejections and to present the rejected claims in better form for consideration on appeal. No claim has been amended in response to the 35 U.S.C. 102(e) and 35 U.S.C. 103(a) rejections. The amendments do not touch on the merits, so the amendments may be admitted without a showing of good and sufficient reasons why the amendments were necessary and were not earlier presented. 37 C.F.R. 1.116.

Claims 1-5, 7-14, 16-23, 25-28 and 30 stand rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. Claims 1, 10, 20, and 25 have been amended to comply with the written description requirement. Withdrawal of the rejection under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement is requested.

Claims 1-5, 7-14, 16-23, 25-28 and 30 stand rejected under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement. Claims 1, 10, 20, and 25 have been amended to comply with the enablement requirement. Withdrawal of the rejection under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement is requested.

Claims 19 and 30 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite. The claims 19 and 30 have been amended to delete the references to canceled claims. Withdrawal of the rejection under 35 U.S.C. 112, second paragraph is requested.

Claims 1-5 and 10-14 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,155,267, to Nelson. Applicant traverses the rejection. The Nelson reference fails to describe, either expressly or inherently, each and every claim element of, and therefore does not anticipate, Claims 1-5 and 10-14.

Nelson discloses an implantable medical device and monitoring method providing at least one sensor output signal to the implantable medical device and chronic data representative of at least one physiological parameter (Abstract). A baseline is established using the chronic data provided over an initial sample time period (Col. 2, lines 57-59). The chronic data is then monitored to detect a change in state of the physiological parameter relative to the baseline (Col. 2, lines 52-64). Data associated with detected changes in state is stored within the implantable medical device (Col. 4, lines 53-59). Only detected changes in state are recorded and the chronic data received by the monitoring device is discarded (Col. 4, lines 59-61)

Nelson fails to describe, teach or suggest each and every claim element of Claims 1 and 10. Specifically, Nelson fails to teach or suggest measuring qualitative values, such as quality of life measures recorded by the individual patient. Instead, Nelson teaches monitoring quantitative chronic data, such as from an oxygen sensor and a pressure sensor (Col. 10, lines 28-42). As well, Nelson fails to teach or suggest storing reference or updated physiological measures and one or more reference or updated quality of life measures into a patient care record. Moreover, Nelson fails to teach or suggest comparing updated physiological and quality of life measures respectively to reference physiological and quality of life measures. Therefore, the Nelson reference fails to describe all the claim limitations and does not anticipate Claims 1 and 10.

Claims 2-5 are dependent on Claim 1 and are patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Similarly, Claims 11-14 are dependent on Claim 10 and are patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Accordingly, the Nelson reference fails to describe, either expressly or

inherently, each and every claim element of Claims 1-5 and 10-14. As Nelson fails to anticipate Claims 1-5 and 10-14, withdrawal of the rejection for anticipation under 35 U.S.C. 102(e) is requested.

Claims 1-5, 10-14, 20-23 and 25-28 stand rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,724,983, to Selker et al (Selker I), in view of U.S. Patent No. 5,603,331, to Heemels et al, and further in view of U.S. Patent No. 6,168,563, to Brown. To establish a *prima facie* case of obviousness: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine the reference teachings; (2) there must be a reasonable expectation of success; and (3) the combined references must teach or suggest all the claim limitations. MPEP § 2143. Applicant traverses the rejection.

The Selker I, Heemels and Brown patents, whether taken singly or in combination, fail to teach or suggest every element of the independent claims. Selker I teaches continuous monitoring using a predictive instrument, preferably by computing a probability of a medical outcome or diagnosis, such as an acute cardiac ischemia, based on monitored clinical features (Col. 1, line 61-Col. 2, line 3). The Selker I device is preferably embodied as a cardiac patient monitoring system, which includes a 12-lead electrocardiograph, waveform analyzer, predictive instrument, and control module (Col. 2, lines 49-52). The waveform analyzer is programmed to analyze ECG waveforms, such as S-T segments, Q waves, and T waves, and to recognize the presence of certain characteristics that are particularly indicative of a cardiac condition (Col. 2, lines 54-60). The device can be programmed to identify the location of a myocardial infarction and can compute the probability that the patient has an acute (sudden) cardiac ischemia (Col. 3, lines 30-42; Col. 4, lines 14-17). Furthermore, Selker I can periodically compute and monitor for changes to any probability of a serious cardiac condition, in addition to the probability of an acute cardiac ischemia (Col. 8, lines 16-28).

Heemels teaches an implantable cardiac rhythm management device for

processing and storing the volume of heart rate variability data (Abstract). An implantable stimulator, such as a pacemaker, defibrillator or monitoring device, processes and logs multiple sets of two-dimensional histogram data for sensed beat intervals and retained for subsequent retrieval via telemetry (Col. 3, lines 9-26). A logarithmic compression algorithm is used to compress the collected data to conserve data memory, processor memory, and power consumption on an implantable pacemaker (Col. 2, lines 26-33). An external programmer may then develop a presentation of the data, including individual or composite histograms (Col. 3, lines 26-30).

Brown teaches a system and method for monitoring and managing a health condition of a patient by using a remotely programmable patient-operable apparatus (Abstract). The programmable patient apparatus provides information to the patient about the patient's health condition and interactively monitors the patient health condition by asking the patient questions and by receiving answers to those questions (Col. 14, line 27-Col. 15, line 16). The patient information may include information supplied by a physiological monitoring device, such as a blood glucose monitor or peak-flow meter, that is physically connected to the remotely programmable patient apparatus (Col. 11, lines 26-61; Col. 15, lines 40-57). However, the physiological monitoring device must provide the data in a serial format in synchronization with clock signals provide by the programmable patient apparatus (Col. 11, lines 61-66).

A *prima facie* case of obviousness has not been shown. Selker I teaches computing and monitoring an acute medical condition, such as cardiac ischemia, that has a sudden and rapid onset. Heemels teaches a cardiac rhythm management device that tracks, outputs and graphs binned heart rate variability data. Brown teaches an apparatus that is limited to accepting physiological measures from physiological monitoring devices through a physical connection. When combined, the three teachings result in a device for monitoring acute medical conditions based on heart variability data collected by an external physiological monitoring device and not patient monitoring using a reference baseline for use in automated patient care, per Claims 1, 10, 20, and 25. Thus, there would be no

reasonable expectation of success when combining Selker I, Heemels and Brown.

Moreover, there is no teaching or suggestion to record and store physiological and quality of life measures during an initial observation period and subsequent to the initial observation period. Selker I, Heemels and Brown teach collecting measures without reference to an initial observation period and not collecting reference physiological and quality of life measures into a reference baseline, per Claims 1, 10, 20, and 25. Thus, Selker I, Heemels and Brown fail to teach or suggest all the claim limitations.

Finally, since Selker I, Heemels and Brown provide teachings which, when combined, would result in an inoperative result, there would be no suggestion or motivation to combine, particularly in the absence of teachings for storing a reference baseline.

Claims 2-5 are dependent on Claim 1 and are patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Similarly, Claims 11-14 are dependent on Claim 10 and are patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Claims 21-23 are dependent on Claim 20 and are patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Claims 26-28 are dependent on Claim 25 and are patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Accordingly, as a *prima facie* case of obviousness has not been shown for Claims 1-5, 10-14, 20-23 and 25-28, withdrawal of the rejection for obviousness under 35 U.S.C. 103(a) is requested.

Claims 7-9 and 16-18 rejected under 35 U.S.C. 103(a) as being obvious over Selker I, in view of Heemels et al, and further in view of Brown, and further in view of U.S. Patent No. 4,852,570, to Levine. Applicant traverses the rejection.

As described above with reference to the obviousness rejection of Claims 1-5, 10-14, 20-23, and 25-28, the Selker I, Heemels, and Brown references fail to provide a suggestion or motivation to combine. Similarly, Levin does not provide a suggestion or motivation to combine. Levin teaches conducting tests using a set

of external transducers to monitor the various body functions of a patient during an exercise program (Col. 10, lines 59-65). The patient's physiological function is then collected and recorded by the transducers. Claims 7-9 are dependent on Claim 1 and are patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Claims 16-18 are dependent on Claim 10 and are patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Accordingly, as a *prima facie* case of obviousness has not been shown for Claims 7-9 and 16-18, withdrawal of the rejection for obviousness under 35 U.S.C. 103(a) is requested.

Claims 19 and 30 are rejected under 35 U.S.C. 103(a) as being obvious over Selker I, in view of Heemels et al, in view of Brown, and further in view of Levine, and further in view of U.S. Patent No. 6,067,466, issued May 23, 2000, to Selker et al. (Selker II). Applicant traverses the rejection.

As described above with reference to the obviousness rejection of Claims 1-5, 10-14, 20-23, and 25-28, the Selker I, Heemels, Brown, and Levin references fail to provide a suggestion or motivation to combine. Claim 19 is dependent on Claim 10 and is patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Similarly, Claim 30 is dependent on Claim 25 and is patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Accordingly, as a *prima facie* case of obviousness has not been shown for Claims 19 and 30, withdrawal of the rejection for obviousness under 35 U.S.C. 103(a) is requested.

The amendment filed August 15, 2003 stands subject to objection for introducing new matter into the disclosure. The specification has been amended to cancel the new matter. Withdrawal of the objection is requested.

The prior art made of record and not relied upon has been reviewed by the applicant and is considered to be no more pertinent than the prior art references already applied.

In conclusion, the amendments present the rejected claims in better form for consideration on appeal pursuant to 37 CFR §1.116(b). Entry of the

amendments is requested. Please contact the undersigned at (206) 381-3900 regarding any questions or concerns associated with the present matter.

Respectfully submitted,

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